

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

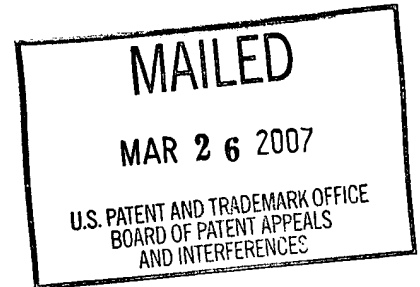
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JILL E. PARKER, JOHNATHAN L. KIEL,
HARDY HOMER, JOHN L. ALLS, and PEDRO J. MORALES

Appeal No. 2007-0306
Application No. 10/828,630

ON BRIEF



Before ADAMS, MILLS and LINCK, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 3-4. Claim 2 is objected to as being a substantial duplicate of claim 1. The only remaining claims, claims 5-10 were withdrawn from consideration as drawn to non-elected subject matter.

We reproduce claims 1, 3 and 4 below:

1. A vaccine strain of *Bacillus anthracis* which is the strain of *Bacillus anthracis* having deposit accession number ATCC PTA-3162.
3. A mutated strain of *Bacillus anthracis* having physiocochemical properties comprising:
 - presence of pX01 plasmid;
 - synthesis of Diazoluminomelanin;
 - sensitivity to Penicillin;
 - ability to be lysed by Cherry gamma phage;
 - non-hemolytic;
 - production of nitrite from nitrate; and,
 - thermal resistance up to about 240 degrees C.

4. The mutated strain of claim 3, further comprising the physiocochemical property of producing delayed onset of death in a laboratory animal, compared to the Sterne strain of *Bacillus anthracis*.

The references relied upon by the examiner are:

Ivins et al. (Ivins)	6,387,665	May 14, 2002
Keim et al. (Keim)	US 2002/0055628	May 9, 2002
Simonson et al. (Simonson)	US 2003/0143636	Jul. 31, 2003

GROUND OF REJECTION¹

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not enable those skilled in the art to practice the claimed invention without undue experimentation.

Claims 3 and 4 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ivins.

Claims 3 and 4 stand rejected under 35 U.S.C. § 102(b) as anticipated by Keim.

We affirm.

DISCUSSION

Claim Grouping:

Appellants have separately argued each claim. Accordingly, we separately discuss each claim before us on appeal.

¹ We decline to consider Appellants' arguments (Brief, pages 6-7) regarding the Examiner's objection to claim 2 (Answer, page 2). Appellants did not petition to have the Examiner's decision reversed, and this board has no authority to review such decisions. See Manual of Patent Examining Procedure (MPEP) § 1002.02(c)(4) and § 1201. Accordingly, the outstanding rejection is not properly before this panel and we have not considered it as part of our deliberations.

Claim Interpretation:

The claims before us on appeal are drawn to a strain of *Bacillus anthracis*. According to appellants' specification (paragraph 22), this "strain of *Bacillus anthracis* is . . . derived from the Sterne vaccine strain of *Bacillus anthracis* . . . [and] is designated the *Bacillus anthracis* AIs/Gifford (Curlicue) strain. . . ." The evidence on this record establishes that several Sterne strains are known in the art. See, e.g., Ivins, column 1, lines 31-34 and Keim, paragraph 36. Appellants, however, fail to identify or discuss any particular Sterne strain. Instead, Appellants disclose only that Sterne, generically, is an attenuated strain that carries the toxin-bearing plasmid (pX01), but not capsule-bearing plasmid (pX02). Specification, paragraphs 6, 8 and 13.

Regarding the "thermal resistance" requirement in Appellants' claims 3 and 4, Appellants direct attention to Figures 1 and 2 (reproduced below) to illustrate "the increased sensitivity of Sterne to heat, and [the] relative thermal resistance of AIs/Gifford." Specification, paragraph 46.

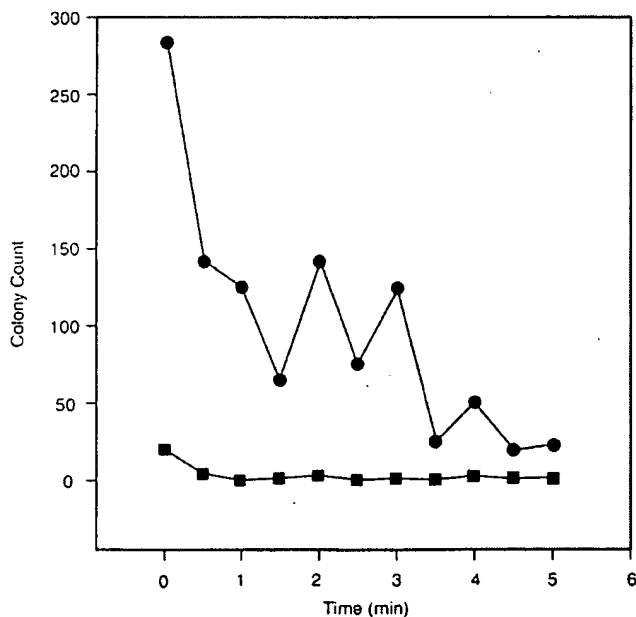


Fig. 1

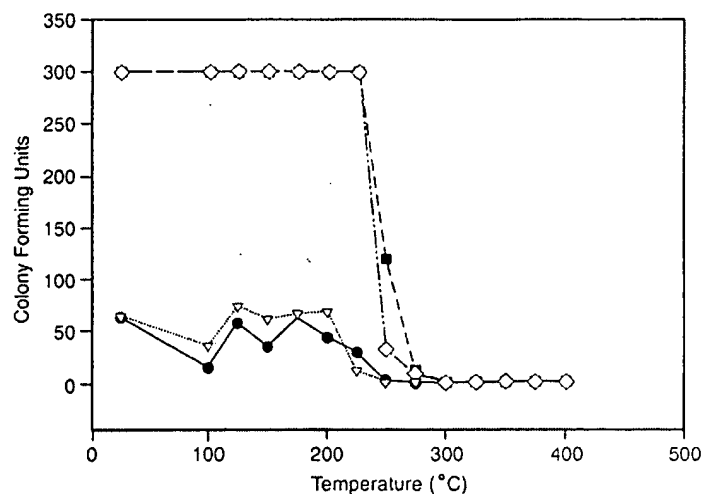


Fig. 2

According to appellants,

In FIG. 1, the sensitivity of Sterne to heating is demonstrated. Starting at about 180°C on blood agar (indicated by circles), Sterne is affected by its exposure to heat. At 275°C, a 1 second exposure has killed all the Sterne spores. Sterne grown on 4X3AT media (as indicated by squares) is less viable than that grown on blood agar because the 4X3AT media is more stringent toward the growth of *Bacillus anthracis*. Sterne on 3AT is affected by heat starting at about 130°C. Sterne is no longer viable after a 1 second exposure at 280°C.

The thermal resistance of Alls/Gifford is demonstrated in FIG. 2. Starting at about 40°C, on blood agar, Alls/Gifford is affected by its exposure to heat (1 µL of inoculum on blood agar, as indicated by circles). Fifty microliters of Alls/Gifford grown on 4X3AT media (as indicated by diamonds) is affected by heat starting at about 240°C. Results for 1 µL of inoculum on 4X3AT media (as indicated by triangles) and 50 µL of inoculum on blood agar (as indicated by squares) are also illustrated. At 300°C, a 1 second exposure has killed all of the Alls/Gifford spores on both media.

Specification, paragraphs 45-46.

Claims 3 and 4 require that the mutated strain of *Bacillus anthracis* exhibits thermal resistance up to about 240 degrees C. These claims, however, place no restriction on the type of media used to determine thermal resistance. The claims also do not require that all the bacteria or bacterial spores must survive thermal exposure up to about 240 degrees C. Appellants' specification discloses, while the Alls/Gifford strain is affected by exposure to heat when grown on blood agar and 4X3AT media, all Alls/Gifford spores are not killed until they are exposed to a temperature of 300°C for 1 second. Specification, paragraph 46. Likewise, while the Sterne strain is affected by exposure to heat when grown on blood agar and 4X3AT media, it is not until they are exposed to a temperature of 280°C for 1 second that they are no longer viable.

Appellants' specification also discloses the effect heat exposure has on the pX01 plasmid, during serial passage of the Sterne or AIs/Gifford strains. See specification, paragraph 46. Appellants' claims, however, do not require that the mutated strain of *Bacillus anthracis* exhibits thermal resistance over any set period of time or for any number of passages. Appellants' specification also discloses that the thermal sensitivity of the Sterne strain is affected by the presence or absence of carbon dioxide. See specification, paragraph 47. Appellants' claims, however, do not require that the mutated strain of *Bacillus anthracis* exhibits thermal resistance in the presence or absence of carbon dioxide.

Accordingly, as we understand appellants' disclosure the Sterne strains generically, as well as the AIs/Gifford strain, all meet the requirement in claims 3 and 4 of a *Bacillus anthracis* strain that is "thermally resistant" up to about 240 degrees C.

Enablement:

Claim 1 stands rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. Claim 1 is drawn to a vaccine strain of *Bacillus anthracis* having deposit accession number ATCC PTA-3162. According to the examiner, appellants' specification does not provide an enabling description of a vaccine strain. Answer, page 3.

According to the examiner "[a] vaccine 'must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is

not enough.’ In re Wright [sic], 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” Answer, page 4. In this regard, the examiner finds (id.), Simonson explains “that in dealing with anthrax vaccination ‘vaccine efficacy in one animal model cannot be compared to the protection afforded other animal immunized with the same vaccines or challenged with the same anthrax strains. . . .’” Finally, the examiner finds that appellants’ specification fails to provide “working examples demonstrating prevention with the strain of the invention.” To the contrary, the examiner finds that the lethality study of appellants’ example 9 demonstrates that while the Alls/Gifford strain demonstrated a prolonged time to death following infection relative to a “Sterne strain” “the ultimate percent survival in both cases was zero percent.”

According to the examiner (Answer, bridging paragraph, pages 4-5), when considered in light of the factors set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988) the foregoing evidence weighs in favor of a finding that excessive experimentation would be required to practice the claimed invention. We agree.

As we understand appellants’ response (Brief, pages 3-6), the enablement rejection is in error because claim 1 was not intended to be drawn to “a perfected, commercially viable embodiment.” We fail to see appellants’ point. Appellants’ have claimed a vaccine strain of B. anthracis, as opposed to a strain of B. anthracis. We are not persuaded by appellants’ assertion that the rejection is improper simply because appellants’ have not developed the claimed strain of B. anthracis to the point where it can correctly and accurately be characterized

as a vaccine strain. As stated by the Court of Appeals for the Federal Circuit, our reviewing court,

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that “a patent is not a hunting license.” It is not a reward for the search, but compensation for its successful conclusion.) Tossing out the mere germ of an idea does not constitute enabling disclosure.

Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). Appellants’ wish to someday produce an improved anthrax vaccine from the deposited B. anthracis strain (see Brief, bridging sentence, pages 3-4), is insufficient in view of the evidence weighing in favor of the examiner’s position.

We are also not persuaded by appellants’ assertion (Brief, page 5) that Simonson is not relevant to claim 1 because (1) the “reference does not contain the phrase ‘vaccine strain’ that is used in [c]laim 1; and (2) the references “discusses studies of a perfected, commercially viable product”

On reflection we find no error in the enablement rejection on this record. Accordingly, we affirm the rejection of claim 1 under the enablement provision of 35 U.S.C. § 112, first paragraph.

Anticipation:

Ivins

Claims 3 and 4 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ivins.

Claim 3:

The examiner finds that Ivins teaches “B. anthracis ΔSterne-1(pPA102).” Answer, page 5. According to the examiner (id.), appellants’ “specification, page 12, sets forth that Sterne strains, contain the pX01 plasmid, produce diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, and produce nitrite from nitrate.” Regarding the thermal resistance limitation of appellants’ claimed invention, as discussed above, we find the Sterne strains generically, as well as the AIs/Gifford strain, meet the requirement in claim 3 of a Bacillus anthracis strain that is “thermally resistant” up to about 240 degrees C.

For their part appellants assert that Ivins “does not mention thermal resistance.” In response the examiner points out that claim 3 “does not set forth what amount of thermal resistance must be displayed” Answer, page 9. According to the examiner, the survival of a single CFU to exposure of 240 degrees is sufficient to meet the thermal resistance requirement of claim 3. Id. As discussed above, as we understand appellants’ disclosure, the Sterne strains generically, as well as the AIs/Gifford strain, all meet the requirement in claim 3 of a Bacillus anthracis strain that is “thermally resistant” up to about 240 degrees C. Therefore, in addition to having the other physiocochemical properties recited in claim 3, the evidence of record supports a finding that B. anthracis ΔSterne-1(pPA102) will inherently have the physiocochemical property of thermal resistance up to about 240 degrees C as required by appellants’ claim 3. “Under the principles of inherency, if the prior art necessarily functions in accordance

with, or includes, the claimed limitations, it anticipates.” Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.2d 1362, 1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted).

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). For the foregoing reasons it is our opinion that the preponderance of evidence on this record supports a finding that claim 3 is anticipated by Ivins. Accordingly, we affirm the rejection of claim 3 under 35 U.S.C. § 102(b) as anticipated by Ivins.

Claim 4:

In addition to the findings regarding claim 3 the examiner finds (Answer, bridging sentence, pages 5-6) that

since there are multiple Sterne strains of Bacillus anthracis and claim 4 does not recite which particular strain is being compared, strain B. anthracis ΔSterne-1(pPA102) [will] . . . be able to delay the onset of death relative to other random Sterne strains, as there will inherently be a small but normally distributed variation from one strain compared to another.

In response, appellants assert that Ivins does not mention “delayed onset of death”. Brief, page 8. Accordingly, appellants assert that “a prima facie case of anticipation has not been established.” “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.2d 1362,

1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted). This is true, even if the prior art does not mention the particular property or function.

As the examiner explains (Answer, bridging paragraph, pages 9-10), “there are multiple distinct mutant Sterne strains of *Bacillus anthracis* . . .” and claim 4 does not require a comparison to any particular Sterne strain of *Bacillus anthracis*. Accordingly, the examiner has taken the position that *B. anthracis* Δ Sterne-1(pPA102) will have the property of producing delayed onset of death in a laboratory animal, compared to some other Sterne strain of *Bacillus anthracis* as required by appellants’ claim 4. As the examiner explains (Answer, page 10), “each strain will have an inherent but small variation in survival time when compared to each other.” We agree. For their part, appellants make no attempt to dispute the examiner’s assertion or demonstrate that *B. anthracis* Δ Sterne-1(pPA102) will not inherently meet the requirements of claim 4.

Accordingly, we affirm the rejection of claim 4 under 35 U.S.C. § 102(b) as anticipated by Ivins.

Keim

Claims 3 and 4 stand rejected under 35 U.S.C. § 102(b) as anticipated by Keim.

The examiner finds that Keim teaches *B. anthracis* strains Sterne STI-1 and V770-NP1. Answer, page 6. According to the examiner (*id.*), appellants’ “specification, page 12, sets forth that Sterne strains, contain the pX01 plasmid, produce diazolumelanin, sensitivity to Penicillin, ability to be lysed by Cherry

gamma phage, non-hemolytic, and produce nitrite from nitrate.” Regarding the thermal resistance limitation of appellants’ claimed invention, as discussed above, we find the Sterne strains generically, as well as the AIs/Gifford strain, meet the requirement in claim 3 of a *Bacillus anthracis* strain that is “thermally resistant” up to about 240 degrees C.

For their part appellants assert that Keim “does not mention thermal resistance.” Brief, page 8. In response the examiner points out that claim 3 “does not set forth what amount of thermal resistance must be displayed” Answer, page 9. According to the examiner, the survival of a single CFU to exposure of 240 degrees is sufficient to meet the thermal resistance requirement of claim 3. Id.

However, as discussed above, as we understand appellants’ disclosure, the Sterne strains generically, as well as the AIs/Gifford strain, all meet the requirement in claim 3 of a *Bacillus anthracis* strain that is “thermally resistant” up to about 240 degrees C. Therefore, in addition to having the other physiocochemical properties recited in claim 3, the evidence of record supports a finding that *B. anthracis* strains Sterne STI-1 and V770-NP1 will inherently have the physiocochemical property of thermal resistance up to about 240 degrees C as required by appellants’ claim 3. “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.2d 1362, 1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted).

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). For the foregoing reasons it is our opinion that the preponderance of evidence on this record supports a finding that claim 3 is anticipated by Keim. Accordingly, we affirm the rejection of claim 3 under 35 U.S.C. § 102(b) as anticipated by Keim.

Claim 4:

In addition to the findings regarding claim 3 the examiner finds (Answer, bridging sentence, page 7) that

since there are multiple Sterne strains of Bacillus anthracis and claim 4 does not recite which particular strain is being compared, strain [B. anthracis] strains Sterne STI-1 and V770-NP1 [will] . . . be able to delay the onset of death relative to other Sterne strains.

In response, appellants assert that Ivinis does not mention “delayed onset of death”. Brief, page 8. Accordingly, appellants assert that “a prima facie case of anticipation has not been established.” “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” Mehl/Biophile Int’l Corp. v. Milgraum, 192 F.2d 1362, 1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted). This is true, even if the prior art does not mention the particular property or function.

However, as the examiner explains (Answer, bridging paragraph, pages 9-10), “there are multiple distinct mutant Stern strains of Bacillus anthracis . . .” and claim 4 does not require a comparison to any particular Sterne strain of Bacillus

anthracis. Accordingly, the examiner has taken the position that B. anthracis strains Sterne STI-1 and V770-NP1 will have the property of producing delayed onset of death in a laboratory animal, compared to some other Sterne strain of Bacillus anthracis as required by appellants' claim 4. As the examiner explains (Answer, page 10), "each strain will have an inherent but small variation in survival time when compared to each other." We agree. For their part, appellants make no attempt to dispute the examiner's assertion or demonstrate that B. anthracis strains Sterne STI-1 and V770-NP1 will not inherently meet the requirements of claim 4.

Accordingly, we affirm the rejection of claim 4 under 35 U.S.C. § 102(b) as anticipated by Keim.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED



Donald E. Adams
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge



Nancy J. Linck
Administrative Patent Judge

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